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09/626,326	07/26/2000	William G. Hubbard	047542/0197	8619

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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

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DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/626,326

Applicant(s)

HUBBARD ET AL.

Examiner

Teresa E Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-13, 19-33, 39-41 and 57-64 is/are allowed.
- 6) ☒ Claim(s) 14-18, 34-38, 42-56 and 65-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. Receipt is acknowledged of a request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e) and a submission, filed on March 11, 2003.
2. Claims 1-73 are pending and will be examined.

Information Disclosure Statement

3. The information disclosure statement (IDS) was filed on March 11, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

4. Claims 42-56 and 65-73 have a priority date of the provisional application filed on August 13, 1999, as stated by Applicants in paper No. 16 (page 4, first paragraph).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 14-18, 34-38 and 50-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 14-18 are indefinite in claim 14 because claim 14 contains a limitation "finely divided ceramic particles". It is not clear what is encompassed by this limitation. For example, does it mean a narrow size distribution of the particles or does it refer to the way the particles are distributed in the composition?

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B) Claims 34-38 are indefinite in claim 34 because claim 34 contains a limitation “finely divided ceramic particles”. It is not clear what is encompassed by this limitation. For example, does it mean a narrow size distribution of the particles or does it refer to the way the particles are distributed in the composition?

C) Claims 50-54 are indefinite in claim 50 because claim 50 contains a limitation “finely divided ceramic particles”. It is not clear what is encompassed by this limitation. For example, does it mean a narrow size distribution of the particles or does it refer to the way the particles are distributed in the composition?

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Remarks concerning rejections of claims 42-56 and 65-73

8. Before proceeding with art rejections of claims 42-56 and 65-73, it is noted that a dehydrated polysaccharide gel is not a gel anymore, and that a viscosity of the gel before dehydration does not influence the properties of the dehydrated composition containing the dehydrated gel. In addition, properties of ceramic particles such as “biocompatible”, “non-resorbable” and “finely divided” are inherent properties of spherical ceramic particles, therefore a prior art disclosing spherical ceramic particles anticipates a claim to such particles being biocompatible, non-resorbable and finely divided (see MPEP 2112.01).

2112.01 Composition, Product, and Apparatus Claims

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PRODUCT AND APPARATUS CLAIMS — WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.).

See also In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971) (Claim 1 was directed to a parachute canopy having concentric circumferential panels radially separated from each other by radially extending tie lines. The panels were separated “such that the critical velocity of each successively larger panel will be less than the critical velocity of the previous panel, whereby said parachute will sequentially open and thus gradually decelerate.” The court found that the claim was anticipated by Menget. Menget taught a parachute having three circumferential panels separated by tie lines. The court upheld the rejection finding that applicant had failed to show that Menget did not possess the functional characteristics of the claims.); Northam Warren Corp. v. D. F. Newfield Co., 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) (A patent to a pencil for cleaning fingernails was held invalid because a pencil of the same structure for writing was found in the prior art.).

9. Claims 42-44, 48-56 and 65-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Chu et al. (U. S. Patent No. 6,083,522).

Regarding claim 42, Chu et al. teach a hard tissue implant consisting of a resorbable, swellable implant body of a dehydrated biocompatible polymer (= medium for resuspending a biomaterial) (col. 3, lines 40-45). The polymer can be any polymer capable of forming a three-dimensional matrix (col. 4, lines 15-19), or capable of forming a polymer body which is swellable and sufficiently strong (col. 9, lines 58-61). Such polymers include polysaccharides (col. 9, lines

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65, 66). The implant body contains particulate material (= biomaterial) (col. 4, lines 20-22). The implant is inserted directly into a cavity formed in a hard tissue, such as bone (col. 15, lines 14-26).

Regarding claim 43, Chu et al. teach molding of the polymer matrix (col. 12, lines 49-67) and shaping the polymer body into a desired shape, such as a cylinder (col. 13, lines 46-67; col. 14, lines 1-5).

Regarding claim 44, Chu et al. teach chitin, chitosan and hyaluronic acid (col. 9, lines 66, 67; col. 10, line 1).

Regarding claim 48 Chu et al. teach particulate materials made of ceramic, glass or polymers (col. 4, lines 24-28; col. 11, lines 29-38).

Regarding claim 49, Chu et al. teach ceramic particulate materials (col. 4, lines 24-28).

Regarding claim 50, Chu et al. teach ceramic particulate materials (col. 4, lines 24-28) and spherical particles (col. 11, lines 13).

Regarding claims 51 and 52, Chu et al. teach calcium phosphate particles.

Regarding claims 53 and 54, Chu et al. teach calcium triphosphate particles, hydroxyapatite particles and mixtures of the two (col. 4, lines 25-28).

Regarding claim 55, Chu et al. teach a hard tissue implant consisting of a resorbable, swellable implant body of a dehydrated biocompatible polymer (= medium for resuspending a biomaterial) (col. 3, lines 40-45). The polymer can be any polymer capable of forming a three-dimensional matrix (col. 4, lines 15-19), or capable of forming a polymer body which is swellable and sufficiently strong (col. 9, lines 58-61). Such polymers include polysaccharides (col. 9, lines 65, 66). The implant body contains particulate material (= biomaterial) (col. 4, lines 20-22). The implant is inserted directly into a cavity formed in a hard tissue, such as bone (col. 15, lines 14-26). Chu et al. teach drying the molded polymer matrix (col. 13, lines 11-25).

Regarding claim 56, Chu et al. teach a hard tissue implant consisting of a resorbable, swellable implant body of a dehydrated biocompatible polymer (= medium for resuspending a biomaterial) (col. 3, lines 40-45). The polymer can be any polymer capable of forming a three-dimensional matrix (col. 4, lines 15-19), or capable of forming a polymer body which is swellable and sufficiently strong (col. 9, lines 58-61). Such polymers include polysaccharides (col. 9, lines 65, 66). The implant body contains particulate material (= biomaterial) (col. 4, lines 20-22). The implant is inserted directly into a cavity formed in a hard tissue, such as bone (col. 15, lines 14-26). Chu et al. teach drying the molded polymer matrix (col. 13, lines 11-25). Chu et al. teach implanting the dehydrated composition (col. 15, lines 14-25).

Regarding claims 65 and 69, Chu et al. teach additives col. 11, lines 45-67; col. 12, lines 1-12; col. 20, line 49).

Regarding claims 66 and 70, Chu et al. teach PBS buffer (col. 20, line 49).

Regarding claim 67, Chu et al. teach a hard tissue implant consisting of a resorbable, swellable implant body of a dehydrated biocompatible polymer (= medium for resuspending a biomaterial) (col. 3, lines 40-45). The polymer can be any polymer capable of forming a three-dimensional matrix (col. 4, lines 15-19), or capable of forming a polymer body which is swellable and sufficiently strong (col. 9, lines 58-61). Such polymers include polysaccharides (col. 9, lines 65, 66). The implant body contains particulate material (= biomaterial) (col. 4, lines 20-22).

Regarding claim 68, Chu et al. teach a hard tissue implant consisting of a resorbable, swellable implant body of a dehydrated biocompatible polymer (= medium for resuspending a biomaterial) (col. 3, lines 40-45). The polymer can be any polymer capable of forming a three-dimensional matrix (col. 4, lines 15-19), or capable of forming a polymer body which is swellable

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and sufficiently strong (col. 9, lines 58-61). Such polymers include polysaccharides (col. 9, lines 65, 66). The implant body contains particulate material (= biomaterial) (col. 4, lines 20-22).

Regarding claim 71, Chu et al. teach insertion of the implant directly into a cavity formed in a hard tissue, without any further processing, such as grinding or resuspension (col. 15, lines 14-26).

Regarding claims 72 and 73, Chu et al. teach a hard tissue implant consisting of a resorbable, swellable implant body of a dehydrated biocompatible polymer (= medium for resuspending a biomaterial) (col. 3, lines 40-45). The polymer can be any polymer capable of forming a three-dimensional matrix (col. 4, lines 15-19), or capable of forming a polymer body which is swellable and sufficiently strong (col. 9, lines 58-61). Such polymers include polysaccharides (col. 9, lines 65, 66). The implant body contains particulate material (= biomaterial) suspended in a polymer (col. 4, lines 20-22; col. 11, lines 18-25). The implant is inserted directly into a cavity formed in a hard tissue, without any further processing, such as grinding or resuspension (col. 15, lines 14-26).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. and Hubbard (WO 93/15721; cited in the IDS).

A) Claim 45 is drawn to the composition comprising a cellulose polysaccharide, claim 46 is drawn to the cellulose polysaccharide selected from the group consisting of sodium carboxymethylcellulose, agar methylcellulose, hydroxypropyl methylcellulose, ethylcellulose,

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microcrystalline cellulose and oxidized cellulose. Claim 47 is drawn to the cellulose polysaccharide being sodium carboxymethylcellulose.

B) Chu et al. teach a dehydrated composition comprising polysaccharides, but do not teach cellulose polysaccharides, in particular sodium carboxymethylcellulose, agar methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, microcrystalline cellulose or oxidized cellulose.

C) Hubbard teaches a tissue augmentation composition comprising biomaterial suspended in a polysaccharide gel.

Regarding claim 45, Hubbard teaches cellulose polysaccharide (page 21, lines 8-12). Regarding claim 46, Hubbard teaches sodium carboxymethylcellulose (page 21, lines 33, 34), agar methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, microcrystalline cellulose and oxidized cellulose (page 22, lines 6-10).

Regarding claim 47, Hubbard teaches sodium carboxymethylcellulose (page 21, lines 33, 34).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used cellulose polysaccharides, particularly sodium carboxymethylcellulose, of Hubbard in the dehydrated implant of Chu et al. The motivation to do so, provided by Hubbard, would have been that using sodium carboxymethylcellulose enhanced physical and biocompatible properties of the particulate material suspended in the sodium carboxymethylcellulose gel (page 22, lines 10-16).

12. Claims 1-41 and 57-64 are free of prior art. The closest prior art, Leshchiner et al. (U.S. patent No. 5,143,724) teaches gel slurries formed from a polysaccharide (hyaluronan or hylan) gel in aqueous solution, but do not teach the gel having a viscosity between 20,000 to 350,000 centipoise, or the gel as a carrier for a biocompatible tissue augmentation material.

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13. Claims 1-13, 19-33, 39-41 and 57-64 are allowed.
14. Claims 14-18 and 34-38 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS

July 7, 2003

TJ


B. J. FORMAN
PATENT EXAMINER